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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,538	01/10/2002	Abraham J. Domb	PG 100	9167
23579	7590	04/27/2004	EXAMINER	
PATREA L. PABST HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET, N.E. ATLANTA, GA 30309-3400			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/044,538	<b>Applicant(s)</b> DOMB, ABRAHAM J.	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

The amendment filed January 24, 2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 8, 10, 19, 20, 23 and 24 have been amended.
2. Remarks drawn to rejections under 35 USC 112, second paragraph

Claims 1-24 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

The objection to claim 20 has been overcome by amendment.

### ***Claim Rejections - 35 USC § 112***

The rejection of claim 8 advanced in the previous office action has been overcome by amendment. The rejections of claims 10, 12, 23 and 24 are being maintained for reasons of record and as set forth herein below.

Claim 10 has been amended to recite "a spermine". This recitation also includes derivatives of spermine as stated by the applicants in the remarks. If it includes derivatives of spermine then it is unclear as to what derivatives are intended. In the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of derivatized of this invention, the identity of the said

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derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims even though applicants point out to page 11, line 7 of the specification, which recites alkylated spermine. In the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

Claim 12 recites a plurality of amphiphilic residues. It is not clear if the combination recited is between the members of the Markush group or a combination of individual member derivatives of the group. It is also not clear if the term “oligomers” is intended to mean different sizes of polymers. Applicants also state that the term cholesterol would be understood by one of ordinary skill in the art to mean cholesterol and derivatives thereof. If derivatives are intended then, in the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of derivatized of this invention, the identity of the said derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims even though applicants point out to pages 23 and 26 of the specification and additional references which recite cholesterol derivatives.

Claims 23 and 24 are still seen to be duplicates of claim 1. The recitations, “porous matrix” in claim 23 and “cationic” in claim 24 do not narrow the scope further.

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The following new rejections are made of record.

Claims 1, 4-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term composition. But the recitations in 1a-c are drawn to a polysaccharide to which an oligoamine and a hydrophobic or an amphiphilic group are attached to the polysaccharide chain. A polysaccharide with said groups attached is a derivative rather than a composition since an additional component(s) that comprise a composition are absent. It is not clear if applicants intend a composition with additional component(s) or if they intend a polysaccharide comprising the said groups attached to it. The same recitation is seen in claims 4-20.

Claim 4 recites “dextrans” and “alginates” as members of the Markush group. These recitations are seen to include derivatives also. If derivatives are intended then, in the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of derivatized of this invention, the identity of the said derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim 5 recites that the saccharide units are connected by a bond selected from acetal, hemiacetal, ketal, orthoester, amide, ester, carbonate and carbamate bonds. It is not clear what is meant by this recitation. Ether linkages generally connect saccharide units. The recitation is

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interpreted to mean that the oligoamine or the hydrophobic or the amphiphilic groups are connected to the said polysaccharide by the said linkages.

Claims that depend from base claims that are unclear/indefinite are also rendered unclear/indefinite.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10,031,728 ('728 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 2 and 3 are drawn to a composition comprising a polysaccharide chain having saccharide units ranging from 2 to 2000, at least one oligoamine having at least two amino groups grafted to the polysaccharide per each segment of 5 saccharide units and at least one further grafted group which is hydrophobic or amphiphilic grafted covalently to the polysaccharide chain per each segment of 50 saccharide units the group having at least 4 carbons

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and wherein the hydrophobic or the amphiphilic group is complexed with an anionic macromolecule selected from polynucleic acids, proteins and polysaccharides that are anionic and the said composition of claim 2 wherein the anionic molecules are selected from plasmid, open chain polynucleic acid, an oligonucleotide, an antisense, a peptide, a protein, a polysaccharide and combinations thereof. These recitations are seen in claim 1 of the copending '728 application. The only additional recitation seen in claim 1 of the copending is the molecular weight of 2000 daltons for the oligoamine.

Instant claims 1 and 19 are drawn to a composition comprising a polysaccharide chain having saccharide units ranging from 2 to 2000, at least one oligoamine having at least two amino groups grafted to the polysaccharide per each segment of 5 saccharide units and at least one further grafted group which is hydrophobic or amphiphilic grafted covalently to the polysaccharide chain per each segment of 50 saccharide units the group having at least 4 carbons and the composition according to claim 1 (claim 19 is dependent on claim 1 or 2) in combination with cationic and nonionic lipids or polymers. The copending '728 application's claim 1 is drawn to the same polycation composition in association with an anionic macromolecule. Copending claim 16 is drawn to the composition of copending claim 1 in combination with cationic and nonionic lipid or polymers. An overlap is seen between instant claims 1 and 19 and copending claim 1 because of the recitation "cationic and nonionic lipids or polymers". Because of this and similar recitations in dependent claims, there is substantial overlap seen in claims 1-24 of the instant application with claims 1-19 of the copending '728 application.

It would have been obvious to one of ordinary skill in the art that the claims of the instant application and those of the copending application are substantially overlapping. The

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compositions of the instant invention must contain new and distinguishable limitations over the copending application to be patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7, 12, 14, 16-21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al (EP 0370810).

Yamaguchi et al discloses a polysaccharide that is substituted with the group  $\text{OCH}_2\text{CONHCH}_2\text{CH}_2\text{NHR}$  wherein R is a cholesteryloxycarbonyl (hydrophobic or amphiphilic group). This group is substituted at a proportion of 0.5 to three per 100 of sugar units, which corresponds to .25 to 1.5 per 50 sugar units. In  $\text{OCH}_2\text{CONHCH}_2\text{CH}_2\text{NHR}$ , the part underlined is the oligoamine moiety that has at least two amino (NH) groups. Both oligoamine and the cholesteryl group are covalently grafted to the polysaccharide and the amphiphilic cholesteryl group has at least 4 carbon atoms. Ethylenediamine (oligoamine) is used to bond the cholesterol group to the polysaccharide (page 2, lines 27-29, lines 49-52; page3, lines 1-2)(meets limitations of claims 1, 23 and 24). The polysaccharide that can be used in the invention are dextran and pullulan (page 2, lines 43-44)(limitations of claim 4). The cholesterol is connected to the



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***Conclusion***

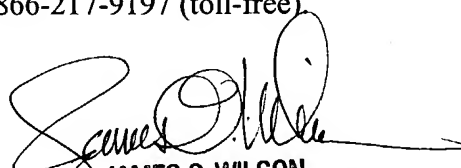
1. Claims 1-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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polysaccharide via an ethylene diamine spacer via an amide bond (page 2, lines 1-5). Yamaguchi also teaches an example wherein aminocarbamoylmethylated pullulan is reacted with cholesteryl chloroformate to form the pullulan comprising the spacer and the cholesteryl group. This also results in the formation of the carbamate linkage. The resulting structure also has the linkages recited in claim 7 (page 4, lines 25-50) (meets limitations of claim 5, 7 and 14). The polysaccharide has cholesterol attached to it (amphiphilic group). Yamaguchi teaches that it could also be a fatty acid group (page 2, lines 27-30)(meets limitation of claim 12). The polysaccharide derivative comprising the oligoamine and the cholesteryl group can be used as a carrier for medicines with water as an additional pharmaceutically acceptable carrier (page 3, lines 40-44). This meets the limitations of claims 16 and 17 since cholesterol group is present in biological systems and is known to move across biological membranes. Since Yamaguchi teaches the use of the polysaccharide of his invention as a carrier for medicines and also teaches the injection of these into blood vessels it is not toxic or immunogenic. Cholesterol is classified under lipids. This meets the limitations of claim 19. The polysaccharide of Yamaguchi has further an  $\text{OCH}_2$  group in the part which connects the oligoamine and the cholesterol group to the polysaccharide. This is a ligand that can facilitate binding (meets limitations of claim 18). The polysaccharide of Yamaguchi with the oligoamine and the cholesterol group is a branched structure (meets limitation of claim 20). Yamaguchi discloses oil in water composition of the polysaccharide of his invention (page 3, lines 36-38). This meets the limitations of claims 21 and 22. Water is a pharmaceutically acceptable carrier.